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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,643	08/21/2003	Adrian Liem	4-32682A	8789
1095	7590	10/19/2005	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			FORD, VANESSA L	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/645,643

**Applicant(s)**

LIEM ET AL.

**Examiner**

Vanessa L. Ford

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1645

**FINAL ACTION**

1. Applicant's amendment and response and declaration filed under 37 C.F.R 1.132 submitted by Douglas Stine are acknowledged. Claims 1-20 and 23-25 have been cancelled. Claim 21 has been amended.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

***Declaration***

3. The declaration filed under 37 C.F.R 1.132 submitted by Douglas Stine is sufficient to overcome the 102(a) art rejection set forth in the previous Office action. See paragraph 4 below.

***Objections/Rejections Withdrawn***

4. In view of Applicant's amendment and response the following rejections are withdrawn:
- a) Objection to the specification, page 2, paragraph 2 of the previous Office action
  - b) Objection to the specification, page 3, paragraph 3 of the previous Office action.
  - c) Rejection of claims 21-22 under 35 U.S.C. 102(a) pages 3-4, paragraph 4 of the previous Office action.
  - d) Rejection of claims 21-22 under 35 U.S.C. 102/103 pages 5-7, paragraph 5 of the previous Office action.

***New Ground of Rejection Necessitated by Amendment***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

It should be noted that the Examiner is viewing the microorganism "*Sphaerophorus necrophorus*" to be the same as "*Fusobacterium necrophorum*". See Berg et al (*EP 0460 480 B1 published January 24, 1996*) (page 2, 2<sup>nd</sup> paragraph). It also noted that that Morck et al., (*U.S. Patent 6,241, 992 B1 published June 5, 2001 (filed September 1998)*) teach that footrot is also known as interdigital phlegmon, interdigital necrobacillosis, foot abscess, foul-in-the-foot or superfoul (column 5). Therefore, the Examiner is interpreting footrot to mean interdigital phlegmon, interdigital necrobacillosis, foot abscess, foul-in-the-foot or superfoul.

5. Claims 21-22 are rejected under 35 U.S.C. 103(a) as unpatentable over Garcia et al (*Canadian Journal Comp Med.*, 38:222-226, 1974) in view of Emery et al (*Aust. Vet J.*, 1985, Vol 62, No. 2, pp 43-46).

Claims 21-22 are drawn to a method of preventing footrot and liver abscesses in bovines caused by infection with *Fusobacterium necrophorum* bacteria, wherein said method is comprised of:

Art Unit: 1645

- (a) growing an isolate of *Fusobacterium necrophorum* bacteria, taken from a bovine species, for successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture having a bacterial count population equal to at least  $1 \times 10^5$  CFU/ml,
- (b) inactivating said *Fusobacterium necrophorum* culture by contacting said culture with formaldehyde;
- (c) forming a vaccine by combining said inactivated *Fusobacterium necrophorum* culture with an amount of diluent; and
- (d) administering at least one dosage of said vaccine subcutaneously to a bovine subject with said dosage of about 1 ml to about 2 ml.

Garcia et al teach a method of preventing liver abscesses in bovines (see the Abstract). Garcia et al teach the *Sphaerophorus necrophorus* was isolated from bovine (page 223). Garcia et al teach that the *S. necrophorus* preparations used to make the vaccine compositions were treated (inactivated) using formaldehyde (page 223). Garcia et al teach that the vaccine composition was formulated using alum (page 223). Garcia et al teach that the antigen suspension was adjusted to 1 mg/ml protein (page 223). Garcia et al teach that the doses range from 1.0 to 20.0 ml (page 223). Garcia et al teach that calves were injected subcutaneously in the neck (page 223). Garcia et al teach that calves were given an initial dose of the vaccine and received a booster injection of dose 0.1 mg/ml protein in 5.0 ml of saline (page 224). Garcia et al teach

Art Unit: 1645

that the vaccine composition comprising *S. necrophorus* cytoplasmic toxoid was the most effective in protecting against liver abscesses due to *S. necrophorus* infection (page 225).

Garcia et al do not teach preventing footrot.

Emery et al teach that the gram-negative *Fusobacterium necrophorum* causes foot abscesses and live abscesses in ruminants (page 43). Emery et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 44). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture" is taught by the prior art.

It would be *prima facie* obvious at the time the invention was made to use a vaccine composition comprising *Fusobacterium necrophorum* in a method of preventing footrot or liver abscesses because Emery et al teach that the association between *Fusobacterium necrophorum* specifically, the strain of biotype AB and lesion of foot abscesses in cattle implies that potential vaccine against infection should be sought from these strains of *F. necrophorum* (page 46). It would be expected barring evidence to the contrary that vaccine composition comprising *Fusobacterium necrophorum* would be effective in preventing infections caused by *F. necrophorum* because Garcia et al has shown that *F. necrophorum* is effective against preventing *F. necrophorum* infections.

Art Unit: 1645

6. Claims 21-22 are rejected under 35 U.S.C. 103(a) as anticipated by Garcia et al (*Canadian Journal Comp Med.*, 38:222-226, 1974) in view of Clark et al (*Aust. Vet J.* 1986, Apr; 63(4):107-10).

Claims 21-22 are drawn to a method of preventing footrot and liver abscesses in bovines caused by infection with *Fusobacterium necrophorum* bacteria, wherein said method is comprised of:

- (a) growing an isolate of *Fusobacterium necrophorum* bacteria, taken from a bovine species, for successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture having a bacterial count population equal to at least  $1 \times 10^5$  CFU/ml,
- (b) inactivating said *Fusobacterium necrophorum* culture by contacting said culture with formaldehyde;
- (c) forming a vaccine by combining said inactivated *Fusobacterium necrophorum* culture with an amount of diluent; and
- (d) administering at least one dosage of said vaccine subcutaneously to a bovine subject with said dosage of about 1 ml to about 2 ml.

Garcia et al teach a method of preventing liver abscesses in bovines (see the Abstract). Garcia et al teach the *Sphaerophorus necrophorus* was isolated from bovine (page 223). Garcia et al teach that the *S. necrophorus* preparations used to make the vaccine compositions were treated (inactivated) using formaldehyde (page 223). Garcia

Art Unit: 1645

et al teach that the vaccine composition was formulated using alum (page 223). Garcia et al teach that the antigen suspension was adjusted to 1 mg/ml protein (page 223). Garcia et al teach that the doses range from 1.0 to 20.0 ml (page 223). Garcia et al teach that calves were injected subcutaneously in the neck (page 223). Garcia et al teach that calves were given an initial dose of the vaccine and received a booster injection of dose 0.1 mg/ml protein in 5.0 ml of saline (page 224). Garcia et al teach that the vaccine composition comprising *S. necrophorus* cytoplasmic toxoid was the most effective in protecting against liver abscesses due to *S. necrophorus* infection (page 225).

Garcia et al do not teach preventing footrot.

Clark et al teach that *Fusobacterium necrophorum* is effective in preventing interdigital necrobacillosis (footrot) (see the Abstract). Clark et al teach that vaccine compositions contained whole cultures, cytoplasmic fractions, cell-free supernatants or killed cells formulated in a mineral oil adjuvant (page 107-108). Clark et al teach that vaccine compositions comprising culture supernatants provided the most protection against footrot in cattle (see the Abstract and page 109). Clark et al teach that *Fusobacterium necrophorum* can be cultured on suitable medium for a period of time up to 18 hours (page 107). Therefore, the prior art teaches the claim limitation "...successive generations in a suitable growth medium for a period of time equal to between 10 hours and 18 hours to form an *Fusobacterium necrophorum* bacteria whole cell culture, with said bacteria culture" is taught by the prior art.

Art Unit: 1645

It would be *prima facie* obvious at the time the invention was made to add the vaccine compositions comprising culture supernatants of *Fusobacterium necrophorum* as taught by Clark et al to the vaccine compositions comprising *Fusobacterium necrophorum* cytoplasmic toxoid of Garcia et al to be used to prevent footrot and liver abscesses in cattle because Garcia et al has demonstrated that compositions comprising *F. necrophorum* cytoplasmic toxoid are effective at preventing liver abscesses in cattle and Clark et al has demonstrated that compositions comprising *F. necrophorum* culture supernatants are effective in preventing footrot in cattle. It would be expected barring evidence to the contrary that vaccine compositions comprising *F. necrophorum* cytoplasmic toxoid and culture supernatants would be effective in preventing infections caused by *F. necrophorum*.

### ***Status of Claims***

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1645

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
October 11, 2005

  
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